Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 7/1/2024
Policy Number: ccp.1491	**Effective Date:** 7/2021 **Revision Date:** June 1, 2024
Policy Name: Intermittent pneumatic compression for peripheral artery disease	

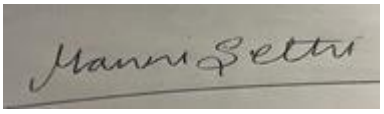
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Intermittent pneumatic compression for peripheral artery disease

Clinical Policy ID: CCP.1491

Recent review date: 6/2024

Next review date: 10/2025

Policy contains: Arterial insufficiency; compression therapy; intermittent pneumatic compression; peripheral artery disease.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Intermittent pneumatic compression is investigational/not clinically proven and, therefore, not medically necessary for treatment of peripheral artery disease.

All other indications for intermittent pneumatic compression in the home setting, excluding chronic venous insufficiency and refractory lymphedema, are investigational/not medically necessary.

Alternative covered services

- Compression bandages or garments.
- Complex decongestive therapy.
- Prescription drug therapy.
- Surgical intervention.

Background

Intermittent pneumatic compression is a therapeutic technique comprised of an inflatable jacket (sleeve, glove, pant leg, or boot) that encloses the limb and an electric air pump that inflates the jacket and pressurizes the enclosed tissues (Zhao, 2014). The alternating inflation and deflation of intermittent or sequential compressions of the sleeves is thought to encourage movement of blood and lymphatic fluid in and out of the pressurized area. Its hemodynamic effects are to promote venous return, increase arterial flow, and reduce edema. In addition, it may enhance fibrinolytic activity and the release of tissue factor pathway inhibitors to block the initiation of blood coagulation.

The U.S. Food and Drug Administration classifies intermittent pneumatic compression as a Class II device that periodically inflates a compressible sleeve around a limb to prevent pooling of blood in the limb (21CFR870.5800). Multiple devices have been approved for commercial use in the United States (U.S. Food and Drug Administration, 2023). These devices may be simple single-chamber or multi-chamber cuffs with limited adjustability or advanced devices that synchronize with cardiac ventricular contraction. They differ in the number and location of air bladders, programmability, patterns for compression cycles, and duration of inflation time and deflation time. They may be portable or battery-powered and may be combined with cold therapy.

There is a growing need for independent, home-based self-management where intermittent pneumatic compression can be administered safely, comfortably, and effectively. Newer-generation devices provide lower delivery pressures, which may expand the indications for use in the home setting.

Findings

For this policy, we included evidence from three systematic reviews (Abu Dabrh, 2015; Moran, 2015; Oresanya, 2018) and two guidelines (Conte, 2019; Gerhard-Herman, 2017) that addressed intermittent pneumatic compression in the home setting to aid wound healing and limb salvage for patients with peripheral artery disease. We also included several systematic reviews and randomized controlled trials for other indications, excluding venous insufficiency or refractory lymphedema.

The overall evidence examining indications for intermittent pneumatic compression in the home setting is very limited in quantity and quality. Few randomized controlled trials have been conducted, and existing trials have significant methodological limitations that call for cautious interpretation of the results. Adverse events and their resolution, particularly those related to increased swelling, were rarely reported systematically across studies.

Differences in the devices and treatment protocols prevent meaningful comparison across studies, and some models assessed in earlier research are no longer commercially available. There is a need for additional higher-quality and adequately powered trials with uniform criteria and standardized treatment protocols and outcome measures to confirm preliminary results using newer-generation devices. Quality of life, functional outcomes, and patient satisfaction would be important considerations to ensure adherence to intermittent pneumatic compression protocols at home.

Current evidence is insufficient to support intermittent pneumatic compression for treatment of peripheral artery disease. A joint guideline of the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies (Conte, 2019) recommended intermittent pneumatic compression in carefully selected patients (e.g., those with rest pain or minor tissue loss) in whom revascularization was not possible. Their recommendations were based on the results of a systematic review that identified one low-quality nonrandomized trial suggesting an association between intermittent pneumatic compression and reduced risk of amputation (odds ratio 0.14, 95% confidence interval 0.04 to 0.55). Both Conte (2019) and Abu Dabrh (2015) called for confirmation in experimental studies.

The American College of Cardiology/American Heart Association guideline (Gerhard-Herman, 2017) issued a weak recommendation for intermittent pneumatic compression to augment wound healing or ameliorate severe ischemic rest pain based on evidence from a systematic review by Moran (2015), which included two controlled before-and-after studies and six case series. Moran (2015) found some improvement in limb salvage, wound healing, and pain management, but the high risk of bias in these studies prevented determination of a true treatment effect. Both Gerhard-Herman (2017) and Moran (2015) acknowledge the need for higher quality evidence to confirm a clinical role.

In another systematic review (Oresanya, 2018) of eight randomized controlled studies (n = 290 patients), high-pressure intermittent limb compression (applied rapidly and sequentially at pressures of > 100 mm Hg to the

calf, foot, or both) increased absolute claudication distance compared to no compression therapy (the mean between-group difference from baseline to follow-up = 125 m, 95% confidence interval 58.38 to 191.63 m; *P* < .01). Limited evidence suggests some subjective improvement in ambulatory function may translate into improved quality of life. However, few studies compared limb compression to other therapies that are considered the standard of care.

A Cochrane review of 34 studies (n = 13,931), mostly of subjects undergoing surgery or admitted with trauma, showed adding drug prophylaxis to intermittent pneumatic compression reduced incidence of pulmonary embolism and deep vein thrombosis (Kakkos, 2022). A similar review of 17 studies (n = 8,796) showed the drug-compression combination reduced incidence of venous thromboembolic events, based on low-quality evidence (Duval, 2022).

In 2024, we found a systematic review of 14 studies that compared intermittent pneumatic compression and graduated compression stockings for preventing venous thromboembolism in surgical patients (Herring, 2023). The number of participants in the 14 studies reviewed, was not provided. Three of seven studies found intermittent pneumatic compression superior to graduated compression stockings, with deep vein thrombosis rates of 0-8% versus 12.5-28.6%, respectively ($p<0.05$) (Herring, 2023). Three of seven studies found combination therapy superior to graduated compression stockings alone in high-risk patients, with deep vein thrombosis rates of 0.5-7.3% versus 12.5-26.4%, respectively ($p<0.05$). Intermittent pneumatic compression had a better safety profile but worse compliance than graduated compression stockings (Herring, 2023). The review concludes intermittent pneumatic compression may be superior to graduated compression stockings alone, and combination therapy may benefit high-risk patients; however, the quality of evidence is low due to differences in study designs, populations, and potential for bias in the included studies (Herring, 2023).

Other indications

For several other indications for intermittent pneumatic compression that have potential home application, we included evidence from three systematic reviews and several individual randomized controlled trials. The trials were conducted primarily in hospitalized patients. The overall quality of the evidence was low with a high risk of bias that prevents determination of a clinical benefit for the following indications:

- To augment circulation during hemodialysis (Torres, 2019; n = seven studies).
- To treat long-term pain, swelling, and instability of ankle sprains (Hansrani, 2015; 12 studies, n = 1,701 total patients, including one study of intermittent pneumatic compression).
- To treat patients (n = 186) after varicose vein surgery (Kappa-Markovi, 2021).
- Alone or with cryotherapy to improve symptomatic knee osteoarthritis (Sari, 2019, n = 89 patients).
- Alone or with cryotherapy to reduce pain, swelling, inflammation, or infection after orthopedic surgery:
    - Rotator cuff repair (Kraeutler, 2015, n = 46 total patients).
    - Total knee arthroplasty (Su, 2012, n = 280 total patients).
    - Anterior cruciate ligament reconstruction (Waterman, 2012, n = 36 total patients).
    - Ankle fracture surgery (Winge, 2017, eight studies; Winge, 2018, n = 153 total patients).
    - Volar plate fixation of distal radial fractures (Alkner, 2018; n = 115 total patients).

References

On May 11, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “leg ulcer/therapy” (MeSH), “compression devices, intermittent pneumatic” (MeSH), “lymphedema/therapy” (MeSH), “intermittent pneumatic compression,”

and “lymphedema pump.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

21CFR870.5800 Compressible limb sleeve.

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Policy updates

6/2021: initial review date and clinical policy effective date: 7/2021

6/2022: Policy references updated.
6/2023: Policy references updated.
6/2024: Policy references updated. No policy changes warranted.